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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,928	11/08/2000	John W. Holaday		9620

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[REDACTED] EXAMINER

NGUYEN, DAVE TRONG

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1632

DATE MAILED: 08/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/707,928	HOLADAY ET AL.
Examiner	Art Unit	
Dave Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 February 0528.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14-29 is/are pending in the application.
 - 4a) Of the above claim(s) 16 and 27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) __ is/are rejected.
- 7) Claim(s) __ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input checked="" type="checkbox"/> Other: _____ . |

Applicant's election with traverse of the species of a source of pulsed electrical energy in the response filed May 28, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed error in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The traversal is that the restriction is not proper because the inventions are not independent and not distinct, and that no undue burden is required to search and examined all of the claims, citing MPEPT 803. The traversal is not found persuasive because the restriction of record is not a group restriction but rather a species restriction. While the invention in the presently pending claims is one invention, the species of pulsed electrical energy and the species of electrical energy being in a variable flux are not overlapped in any and in fact are not the same. A pulse of electrical energy that is applied to the electroporation chamber is not the same as a continuous flow of electrical energy in a variable flux. Thus, a search of an applied pulse of electrical energy which is *per se* not continuous flow of energy source would not necessarily overlap with that of a variable flux of electrical energy being applied to the claimed electroporation chamber.

As such, the species restriction is proper and therefore made final.

Claims 16 and 27 readable on the non-elected species has been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claimed species.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 22-24, readable on the limitation of the genus of "mechanisms for breaking the electrodes prior to the apparatus being removed from the support member whereby the

apparatus cannot be re-used", and the limitation of a "controller" responsive to the rate which the pump moves the biological particles along the fluid flow path and to the interval between pulses of electrical energy, respectively, are not claimed in a specific structure and/or mean that would have been envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 20 embracing any mechanisms for breaking the electrodes prior to the apparatus being removed from the support member whereby the apparatus cannot be re-used, the as-filed specification only provides sufficient description-claims-drawn-to-means that are connected to the electrodes employed in the claimed continuous electroporation chamber when said chamber is mounted to a support member for destroying said electrodes prior to the chamber being removed from the support chamber, e.g., page 24, lines 12-27.

With respect to claims 22-24 readable on any controller responsive to the rate which the pump moves the biological particles along the fluid flow path and to the interval between pulses of electrical energy, the as-filed specification only provides sufficient description of a controlled circuit board employed in the claimed electroporation chamber so as to respond to the rate which the pump moves the biological particles along the fluid flow path and to the interval between pulses of electrical energy, e.g., page 63, lines 3-23.

However, the claims are readable on an enormous numbers of "mechanisms" and/or "controllers", and it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention that are essential for the making and use of the claimed invention; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of "mechanisms" and/or "controllers", which must exhibit the disclosed functions as contemplated by the as-filed specification.

It is not sufficient to support the present claimed invention directed to functional languages because the disclosure of no more than species inert polymers as the first co-dispersant compound as

in the instant case, is simply a wish to know the identity of any and/or all other mechanisms" and/or "controllers", as embraced by the claims. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming unspecified structures of mechanisms" and/or "controllers", which must possess the properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed mechanisms" and/or "controllers", that must exhibit the contemplated functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 20, 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to:

The electroporation chamber as recited in claim 20, wherein the limitation of "mechanisms" is amended to

-- means that are connected to the electrodes employed in the claimed continuous electroporation chamber when said chamber is mounted to a support member for destroying said electrodes prior to the chamber being removed from the support chamber --; and

The electroporation chamber as recited in claims 22-24, wherein the recited "controllers" is amended to -- a circuit board --.

The specification does not reasonably provide enablement for the presently pending claims encompassing any other claimed embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of mechanisms and/or controllers as recited in the claims, particularly in view of the reasons set forth above, one skilled in the art would not known how to use and make the entire breadth of the claimed invention so that it would operate as intended.

Claims 22-26, 28-29 are rejected under 35 USC 102(a) as being anticipated by, or in the alternative, under 35 USC 103(a) as being unpatentable over Nicolau (WO 94/21117).

The claims embrace a continuous electroporation chamber comprising walls defining a fluid flow path, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles.

Nicolau teaches the same on page 49, claim 21 cited on page 48, claims 1-7 cited on pages 42 and 43, pages 24 and 26, pages 35-40. With respect to the pump for moving the biological particles, Nicolau teaches the same on pages 21-22. The use of an electrical pulse from a pulse generator is disclosed on pages 25-26. Electrical controlled board and/or mechanical valves so as to link the chamber, pulse generator, the peristaltic pump, the blood cooling system are also disclosed on page 34 and page 40

To the extent that the reference does not teach "continuous band electrodes", such limitation would have been obvious as a minor modification and matter of design choice. One with a high level of skill in the art would have been motivated to employ minor modification as a matter of design choice as long as the modifications are within the framework of the invention, particularly in the absence of evidence to the contrary.

Claims 25-26, 28-29 are rejected under 35 USC 102(e) as being anticipated by Meserol (US Pat NO. 6,090,617, which has a distinct inventive entity having a common inventor, i.e., Meserol).

The claims embrace a continuous electroporation chamber comprising walls defining a fluid flow path, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles.

The claims of Meserol do embrace a continuous electroporation chamber comprising walls defining a fluid flow path, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path. In addition, the specification on columns do discloses a continuous electroporation chamber comprising walls defining a fluid flow path, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles.

Thus, Meserol teaches and anticipates the examined claims.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-15, 17-26, 28-29 are rejected under 35 USC 102(e) as being anticipated by Meserol (US Pat No. 5,720,921, which has a different inventive entity wherein the common inventor is Meserol).

With respect to the enabling claimed embodiment, Meserol teaches a continuous electroporation chamber comprising walls defining a fluid flow path wherein the walls are partly elastically deformable and rigid, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles, and wherein the chamber further comprises means that are connected to the electrodes employed in the claimed continuous electroporation chamber when said chamber is mounted to a support member for destroying said electrodes prior to the chamber being removed from the support chamber, e.g., see entire disclosure, particularly the claims, abstract, the cited Figure on the front page, column 15 with respect to the electric field, column 20, lines 41-49 as to the cooling chamber, columns 20-21 with respect to the making of the electrodes, column 25 with respect to the making of a motor that can be used to destroy the electrodes after being used, columns 25 and 27, last paragraph as to the disclosure of the electrical board for monitoring and controlling all of the mechanical means that are necessary to operate within the framework of the invention.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-15, 17-26, 28-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of Meserol (US Pat No. 5,720,921, which has a different inventive entity wherein the common inventor is Meserol).

Although the conflicting claims are not identical, the examined claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims.

The examined claims and the claims of the patent when read in light of the disclosure of the patent are drawn to

a continuous electroporation chamber comprising walls defining a fluid flow path wherein the walls are partly elastically deformable and rigid, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles, and wherein the chamber further comprises means that are connected to the electrodes employed in the claimed continuous electroporation chamber when said chamber is mounted to a support member for destroying said electrodes prior to the chamber being removed from the support chamber. The following portions of the specification of the patent are cited to support the above claimed invention: the cited Figure on the front page, column 15 with respect to the electric field, column 20, lines 41-49 as to the cooling

chamber, columns 20-21 with respect to the making of the electrodes, column 25 with respect to the making of a motor that can be used to destroy the electrodes after being used, columns 25 and 27, last paragraph as to the disclosure of the electrical board for monitoring and controlling all of the mechanical means that are necessary to operate within the framework of the invention. In view of the metes and bounds of the claims of the reference patent that embrace the examined claims, particularly when read in light of the supported portions of the specification of the patent, one of ordinary skill in the art would have been motivated to have made the electroporation chamber as claimed because of the claims issued in the patent.

Claims 22-26, 28-29 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of Meserol (US Pat No. 5,720,921, which has a different inventive entity wherein the common inventor is Meserol).

Although the conflicting claims are not identical, the examined claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims.

The examined claims and the claims of the patent when read in light of the disclosure of the patent are drawn to

a continuous electroporation chamber comprising walls defining a fluid flow path, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles.

While the claims of the patent do not explicitly embrace the circuit board and/or mechanical means so as to respond to the pump rate, the metes and bounds of the claims from the patent do embrace such limitation particularly when read in light of the specification. The following portions of the specification of the patent are cited to support the above claimed invention: the cited Figure on the front page, column 15 with respect to the electric field, column 20, lines 41-49 as to the cooling chamber, columns 20-21 with respect to the making of the electrodes, column 25

with respect to the making of a motor that can be used to destroy the electrodes after being used, columns 25 and 27, last paragraph as to the disclosure of the electrical board for monitoring and controlling all of the mechanical means that are necessary to operate within the framework of the invention. In view of the metes and bounds of the claims of the reference patent that embrace the examined claims, particularly when read in light of the supported portions of the specification of the patent, one of ordinary skill in the art would have been motivated to have made the electroporation chamber as claimed because of the claims issued in the patent.

No claims are allowed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632


DAVE T. NGUYEN
PRIMARY EXAMINER